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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,691	05/24/2004	Itzhak Bentwich	050992.0400.01USCP	3690
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EXAMINER				
WOLLENBERGER, LOUIS V				
ART UNIT		PAPER NUMBER		
1635				
MAIL DATE		DELIVERY MODE		
05/26/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/709,691

Applicant(s)

BENTWICH ET AL.

Examiner

Louis Wollenberger

Art Unit

1635

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23, 25, 31, 33, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 33 and 40 is/are allowed.
- 6) ☒ Claim(s) 23, 31 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 3/16/2010 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 12/16/2009 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Applicant's amendments to the claims filed 3/16/2010 are acknowledged. With entry of the amendment, Claims 23, 25, 31, 33, 39, and 40 are pending and under consideration.

Specification

The objection to the specification is withdrawn in view of Applicant's amendment to the specification, filed 3/16/2010. The amendment has been entered into the application.

Claim Rejections - 35 USC § 112, first paragraph (new matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 31, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Adequate written description support is not found in the instant application for the genus of isolated nucleic acids defined by parts (b)-(f) of claim 23, wherein the sequence of the nucleic

acid is selected from “nucleotides 1-21 of SEQ ID NO:348,” “nucleotides 1-22 of SEQ ID NO:348,” or “a sequence of 23-24 nucleotides, wherein nucleotides 1-22 of said sequence consist of SEQ ID NO:348.”

MPEP 2163, Section II, Part A, states in part that there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. The purpose of the written description requirement is “to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.” MPEP 2138.05, I.

In the instant case, in the remarks filed 3/16/2010, Applicant points to paragraph 284 of the specification as support for the claimed nucleic acids. The Examiner respectfully disagrees that this paragraph demonstrates Applicant had conceived and was in possession of the 21, 23, and 24-nucleotide sequences of instant SEQ ID NO:348 as now claimed. The disclosure at paragraph 284 must be read in context with surrounding disclosure to fairly consider what it does or does not represent to the public regarding applicant’s invention. The paragraph is included in a section of the specification explaining reasons why one of skill might fail to detect a predicted miRNA in a cell. The disclosure cites the sensitivity of the testing method, the expression level of the miRNA, and specificity of the detection primer. Paragraph 284 states that the 3’ terminus of observed GAM RNA sequences is often truncated or extended by one or two nucleotides, it does not represent to the public that the observed GAM RNA sequence for SEQ ID NO:348 is truncated or extended, or that the GAM RNA sequence for SEQ ID NO:348 is both truncated

and extended as now claimed. The statement at paragraph 284 merely postulates that the bioinformatically predicted sequence may differ from that actually expressed in the cell by one or two nucleotides at the 3' terminus. There is in fact no evidence to show this is or was found to be the case with SEQ ID NO:348 for any cell or tissue. The statement at paragraph 284 is speculative and nothing more than a possibility one of skill should keep in mind when designing primers to detect any of the bioinformatically predicted GAM RNAs in any cell or tissue. The specification discloses a 22-nucleotide RNA sequence consisting of SEQ ID NO:348 bioinformatically predicted to be a mature miRNA.

It is also respectfully pointed out that as now written, claim 23 is subject to much broader interpretation than is reasonably supported by the application as filed. Notwithstanding the discussion above, the limitations in parts b and c may be mistaken for recitation of alternatives themselves, wherein the sequence is selected from any of nucleotides 1-21 or 1-22 of SEQ ID NO:348, broadening the scope of the claim far beyond what Applicant invented and intends to claim to include any isolated nucleic acid sequence consisting of any sequence from nucleotides 1-21 or 1-22 of SEQ ID NO:348. As written, the claim would appear to recite numerous possible sequences, none of which are described by paragraph 284 or the application as a whole.

Accordingly, the instant claims as a whole are rejected for lack of written description support because one of skill would not recognize applicant was in possession of the product siRNAs now claimed at the time of filing. Dependent claims are rejected therefor.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Primary Examiner, Art Unit 1635
May 19, 2010